



Canadian Blood Services
Société canadienne du sang

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2018-07-13
CBS Control #: CBS6217
HPFB File #: C1892-100390
REF: H-1819-SAS-L

Ms. Shelley Smyth
Regulatory Compliance and Enforcement Specialist
Regulatory Operations and Regions Branch
Health Canada
300-391 York Avenue
Winnipeg, Manitoba
R3C 4W1

Dear Ms. Smyth:

Re: Responses to Health Canada Inspection of Licensed Activities at Regina Operations
2018-06-18 to 2018-06-20

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2018-06-29.

Section 95 - Operating Procedures

1. Some operating procedures were not always followed.

During the review of records in ePROGESA it was noted that contrary to SOP 01 144 v.8, "Screen Donor" and MAN 01 200 "Donor Selection Criteria Manual" Section W, V.8 Amendment 9, the height and weight was not obtained for a first time donor less than 23 years of age, donation #C05301870744800Y, at the mobile clinic with code S0107 from 22/05/2018.

The height and weight requirement for first time donors under the age of 23 as per MAN 01 200 'Donor Selection Criteria Manual' and SOP 01 144 'Screen Donor' has been reviewed with all Clinic Services staff in Regina and individually with the staff member involved on 2018-06-28.

An assessment is being performed to determine if eProgesa can be configured to make a height and weight entry of new donors between 17 and 23 mandatory.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please reference the above CBS control number in any correspondence.**

Sincerely,

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affairs
Fax Number: 613-739-2505

cc: Hugo Tremblay
Supervisor – Blood, Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch

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